REMARKS

Applicant's counsel thanks the Examiner for the careful consideration given the application. Applicants respectfully request reconsideration of the present Patent Application, particularly in view of the above Amendments and following remarks.

Amendments to the Claims

Claims 1-10 have been amended to address the Examiner's objections and to improve the claim language for the sake of clarity. Particularly, applicant has added a statement at the beginning of each step in order to clarify that the steps are carried out sequentially by using the result of the previous step. The fact that all the steps of the claimed process are interrelated is clear upon reading the description, particularly from page 8, lines 4 to page 11, line 2. The other amendments are self-explanatory. No new matter has been added to the claims by the above Amendments.

Claim Rejections – 35 U.S.C. § 112

The amendments submitted herewith should dispose of the rejections under 35 U.S.C. § 112. No specific comments are believed to be necessary.

Claim Rejections – 35 U.S.C. § 103(a)

The Examiner's rejection of Claims 1, 3 and 5-10 under 35 U.S.C. § 103(a) as being unpatentable over D'Urso (US 5,741,215) in view of Taboas et al (US 2003/0006534) is respectfully traversed in view of the following arguments.

D'Urso relates to a method for stereolithographic construction of implantable surgical prosthesis and/or an anatomical pathology model, said method comprising the steps of:
inputting into a data storage means scanning data relating to internal and/or external surfaces of anatomical pathology;
computing the stored scanning data according to a predetermined algorithm to reconstruct a plurality of two dimensional cross-sectional images of the anatomical pathology;
computing said plurality of two dimensional cross-sectional images according to a predetermined algorithm to generate a three dimensional coordinate data set for the anatomical pathology;

and generating a three dimensional representation of said anatomical pathology by sterolithographic modeling of a cross linkable liquid polymer using selected sequential two dimensional coordinate data sets computed in preselected planes from said three dimensional coordinate data set.

According to D'Urso the above method can be implemented according to different techniques. Among them, that represented in Figure 7 appears to be the most closely related to the subject matter claimed in the present application. As explained at col. 9, lines 3-38 of D'Urso, after establishing a three dimensional coordinate data set for a region surrounding the defect, highly accurate boundary definitions are obtainable for the edge of the effect aperture as well as the cross sectional contours of region. A model for the defect is then created by using a three-dimensional stereolithographic technique. Once a satisfactory fit of model in the defect has been achieved, a cranioplastic implant may then be manufactured from the model, in acrylic or hydroxyapatite or other suitable material.

Therefore, the teaching derivable from D'Urso differs from the method according to the present invention at least for the following features:

(i) D'Urso does not show the step of forming a negative mould starting from a model of the patient's bone defect, which is a negative of the patient's bone defect, which is then used to produce the sintered ceramic device; conversely, D'Urso teaches producing a ceramic device directly from the model of the defect obtained by a three-dimensional stereolithographic technique;

(ii) D'Urso does not teach producing a sintered ceramic semi-finished product whose dimensions and shape are slightly larger than those of the bone defect, and then subjecting the semi-finished product to mechanical processing and manual finishing to obtain the finished ceramic product having precise dimensions and shape of the bone defect; conversely, D'Urso teaches precisely fitting the model to the defect, and only subsequently producing the prosthetic ceramic device on the basis of the precise model;

(iii) D'Urso does not teach producing a sintered ceramic semi-finished product having a controlled and interconnected porosity of from 30 to 90%, said porosity having a bimodal distribution of the pore dimensions in a first range of from 0.1 to 125 microns and in a second range of from 125 to 2500 microns, as instantly claimed.

The above differences cannot be derived by the other references cited by the Examiner.

The secondary reference, Taboas, et al, relates to a method of fabricating tissue scaffolds and other similar structures, which includes computationally designing the desired structure, fabricating a mold for the desired structure, casting the desired structure in the mold, and removing the mold from the desired structure. Methods for post modification of the desired structure are presented. The step of computationally designing the desired structure preferably includes at least one computer aided design technique and/or an image based design technique. The step of fabricating the mold for the desired structure preferably includes solid free form techniques such as 3D printing, fused deposition, stereolithography, selective laser sintering, direct material deposition, or layered object manufacturing. The step of post modification of the structure preferably includes stabilized plasma functionalization.

Therefore, Taboas, et al. does not teach producing a negative mould of the patient's bone defect starting from a model of the bone defect itself, which in turn is obtained from a prototype resin model of the interested region by means of a three-dimensional stereolithographic technique.

Moreover, differently from what is alleged by the Examiner, Taboas, et al. does not teach producing a sintered ceramic semi-finished product having a controlled and interconnected porosity having a bimodal distribution as instantly claimed. At paragraphs [0022] – [0027] of Taboas, et al., some ranges of pore dimensions are given which, however, do not suggest the use of a bimodal distribution according to the present invention.

Therefore, even combining the primary reference D'Urso with Taboas, et al, a person skilled in the art cannot arrive at the claimed invention.

Additionally, the Examiner rejects Claim 2 under 35 U.S.C. § 103(a) as being unpatentable over D'Urso in view of Taboas et al., as applied to Claim 1, and further in view of Cummings et al. (US 2004/0152034). This rejection is clearly moot in view of the above arguments relating to D'Urso and Taboas et al.

Cummings et al. relates to an article in the form of a dental article or an orthodontic appliance comprising a ceramic, glass or glass-ceramic of defined compositions, and to a method of making the above dental article or an orthodontic appliance which comprises the steps of:

providing a dental or orthodontic mill blank;
carving a dental or orthodontic mill blank, wherein the dental mill blank comprises the above glass or glass-ceramic.

As disclosed at paragraph [0255] of Cummings, et al., a dental coping was milled from the small cylinder of the above material on an automated milling system, by using a metal-plated diamond wheel and a cylindrical bur. Therefore, the metal-plated diamond wheel is used on a cylinder to obtain the final dental article without using any of the production steps according to the present invention.

Cummings, et al., does not suggest at least the following features: (i) the step of forming a negative mould starting from a model of the patient's bone defect, which is a negative of the patient's bone defect, which is then used to produce the sintered ceramic device; and (ii) the step of producing a sintered ceramic semi-finished product whose dimensions and shape are slightly larger than those of the bone defect, and then subjecting the semi-finished product to mechanical processing and manual finishing to obtain the finished ceramic product having precise dimensions and shape of the bone defect.

Therefore, even combining D'Urso with Taboas, et al. and then with Cummings, et al., a person skilled in the art cannot arrive at the claimed invention.

Taking into account the above arguments, the non-obviousness of the claimed invention is apparent. It is clear from the foregoing that the claims as now presented define over the prior art. A Notice of Allowance is accordingly now in order and is respectfully requested. If any additional fees are required by this communication, please charge such fees to our Deposit Account No. 16-0820, Order No. BUG5-41416.

Respectfully submitted,
PEARNE & GORDON LLP

By John P. Murtaugh
John P. Murtaugh, Reg. No. 34226

1801 East 9th Street, Suite 1200
Cleveland, OH 44114-3108
Phone: 216-579-1700

Date: 11-8-10